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**UNITED STATES DISTRICT COURT
DISTRICT OF OREGON**

**STEVEN LOUIS FLOREA and KIMBER LEE FLOREA, co-administrators of the
ESTATE OF VASILLE LOUIS FLOREA,
deceased,**

Plaintiffs,

v.

**ETHEX CORPORATION, a Missouri
Corporation, and K-V
PHARMACEUTICAL COMPANY, a
Delaware Corporation,**

Defendants.

**COMPLAINT
(Wrongful Death Action 28 USC §1332)
Strict Product Liability; Negligence;
Punitive Damages**

DEMAND FOR JURY TRIAL

PLAINTIFFS' COMPLAINT

Plaintiffs Steven Louis Florea and Kimber Lee Florea, Co-Administrators of the Estate of Vasilie Louis Florea, deceased, allege:

I. INTRODUCTION

1. Plaintiffs bring this action against the Defendants for designing, manufacturing, producing, supplying, inadequately inspecting, testing, selling and distributing dangerous, defective, misbranded and adulterated Morphine Sulfate tablets (hereinafter referred to as "Morphine")

containing an amount of the drug's active ingredient different from and/or exceeding the dose set forth on the drug's label and in some cases exceeding the dose approved for medical treatment in humans. By reason of the wrongful conduct of the Defendants and the dangers posed by the potential for overdoses or misdosing of the drug, a national recall of certain lots of Morphine tablets has been initiated in the United States.

II. JURISDICTIONAL STATEMENT

2. Jurisdiction is based on diversity of citizenship pursuant to 28 U.S.C. §1332. The decedent, Vasilie Louis Florea ("Decedent"), was at all material times a resident of the State of Oregon. Defendant Ethex Corporation is a corporation incorporated under the laws of the State of Missouri with its principal place of business in Missouri. Defendant K-V Pharmaceutical Company is a corporation incorporated under the laws of Delaware with its principal place of business in Missouri. The incident giving rise to this action occurred in the State of Oregon. The amount in controversy, exclusive of interest and costs against Defendants exceeds \$75,000. Plaintiffs also hereby invoke the pendent jurisdiction of this Court to hear and decide claims arising under state law.

3. Venue is proper pursuant to 28 U.S.C. § 1391. Defendants have sufficient minimum contacts in the state of Oregon or otherwise intentionally avails themselves of the consumer markets within Oregon through the promotion, sale, marketing and/or distribution of its products in Oregon to render the exercise of jurisdiction by this court permissible under traditional notions of fair play and substantial justice.

III. PARTIES

A. PLAINTIFFS

4. Plaintiff, Steven Louis Florea, co-administrator of the Estate of Vasilie Louis Florea, individually and on behalf of the Estate of the Decedent, is a co-administrator of his Estate duly appointed by Letters of Administration entered on April 9, 2008 in the Circuit Court of the State of Oregon for Jackson County. Plaintiff Steven Louis Florea is also an individual residing in the State of Oregon.

5. Plaintiff, Kimber Lee Florea, co-administrator of the Estate of Vasilie Louis Florea, individually and on behalf of the Estate of the Decedent, is a co-administrator of his Estate duly appointed by Letters of Administration entered on April 9, 2008 in the Circuit Court of the State of Oregon for Jackson County. Plaintiff Kimber Lee Florea is also an individual residing in the State of Oregon.

6. The Decedent, Vasilie Louis Florea, was at all relevant times a resident of the State of Oregon. At the time of his death, he was 81 years old and had a reasonable life expectancy of 6.8 years.

B. DEFENDANTS

7. Defendant K-V Pharmaceutical Company is a corporation incorporated under the laws of Delaware with its principal place of business located at 2503 S. Hanley Road, St. Louis, Missouri 63144.

8. Defendant Ethex Corporation is a corporation incorporated under the laws of Missouri with its principal place of business located at One Corporate Woods Drive, St. Louis, Missouri 63044.

9. At material times hereto, the Defendants:

a. were, and are, engaged in the business of the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Morphine tablets in the United States and Oregon either directly or indirectly through third-parties or related entities;

b. were, and are, in the business of profiting from the in the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing, advertising, promotion, supply, releasing and/or distribution of Morphine tablets;

c. conducted continuous and substantial business in the state of Oregon; and,

d. acted and gained knowledge itself and by and through its various agents, servants, employees, and/or ostensible agents.

10. At all times relevant and material hereto, Defendants have conducted continuous and substantial business in the state of Oregon.

11. At all times relevant and material hereto, Defendants acted and failed to act and gained knowledge itself, and by and through its various agents, servants, employees and/or ostensible agents.

12. The Defendants are drug companies, that upon information and belief, engaged in the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing, advertising, promotion, supply, releasing and/or distribution of Morphine tablets containing an amount of the drug's active ingredient, morphine sulfate, different from and/or exceeding the dose on the label.

13. At all times relevant to this action, Defendants knew, and/or had reason to know, that the recalled Morphine tablets were not safe for the patients for whom the drug was prescribed, such as the Decedent, because an excess dose of morphine sulfate, or a dose different from the dose on the label, can cause serious medical problems and in certain patients, catastrophic injuries and death.

IV. FACTUAL ALLEGATIONS

14. The Decedent purchased and ingested Morphine tablets pursuant to a physician's prescription and suffered serious personal injuries including death on or about May 13, 2007, as a result of said ingestion of said Morphine tablets.

15. In or around June, 2008 Decedent and/or his family were sent and received an "IMPORTANT SAFETY NOTICE- MORPHINE SULFATE 30 MG & 60 MG ER TABLETS" from Safeway Pharmacy where Decedent purchased Defendants' Morphine tablets (hereinafter referred to as the "Recall Notice"). The Recall Notice informed that:

Our records indicate that you received prescription #2207463, for Morphine Sulfate tablets sometime after June 1, 2006. We are sending this letter to notify you of the following important information concerning a voluntary manufacturer's recall of Morphine Sulfate 30 mg and 60 mg extended release (ER) tablets.

Recall Information: ETHEX Corporation, a manufacturer of Morphine Sulfate tablets, has informed pharmacies across the United States, including Safeway pharmacies, that certain lots of Morphine Sulfate 30 mg and 60 mg ER tablets supplied to pharmacies between June 2006 and May 2008 are being recalled as a precaution due to the possible presence of oversized tablets. Oversized tablets may contain as much as two times the labeled level of active morphine sulfate.

Product Description: The Morphine Sulfate 60 mg ER tablet is a white oval tablet with a "60" on one side, and "E" on the reverse. The Morphine Sulfate 30 mg ER tablet is a pink oval tablet with a "30" on one side, and "E" on the reverse.

Safety Information: To date, the manufacturer has not received any reports of unexpected side effects or injury. However, morphine may have life-threatening consequences if overdosed. Those consequences can include respiratory depression (difficulty or lack of breathing), low blood pressure, apnea, and hypotension.

16. Unfortunately Defendant's recall of its defective Morphine tablets was too late. The Recall Notice was received after Decedent had died on May 13, 2007.

17. On or about May 19, 2008, the United States Food and Drug Administration ("FDA") announced a Class I Recall that included all 30 mg and 60 mg Morphine Sulfate Extended Release tablets (hereinafter referred to as "Morphine" and/or "Recalled Morphine") manufactured by Defendants between June 14, 2006 and April 8, 2008, and distributed by Defendants between September of 2006 and May of 2008.

18. According to the FDA, the "Product Public Reason for Recall" for Defendants' recall of morphine sulfate was "super-potent, over-sized tablets."

19. During inspections of Defendants' manufacturing facilities between December 15, 2008 and February 2, 2009, the FDA found thirty-five (35) separate deviations from the current Good Manufacturing Practice ("CGMP") requirement of the Food, drug and Cosmetic Act ("FDCA").

20. During inspections of Defendants' manufacturing facilities between December 15, 2008 and February 2, 2009, the FDA found that Defendants were manufacturing multiple drug products that had not been approved by the FDA, in violation of 21 U.S.C. § 355.

21. During each FDA inspection of Defendants' manufacturing facilities in April of 2003, January of 2004, January of 2005, March of 2006, April of 2007, March of 2008, August of 2008, and February of 2009, the FDA notified Defendants of multiple violations of the CGMP. In response

to the FDA's notification, Defendants expressed their desire to correct the deficiencies, but failed to do so.

22. The FDA issued a Warning Letter to Defendant K-V Pharmaceutical Company on May 9, 2000, identifying numerous CGMP violations found during FDA's February/March 2000 inspections of Defendants' facilities. The Warning Letter emphasized the serious nature of the CGMP violations at Defendants' facilities and informed Defendants that failure to correct the violations could lead to regulatory action, including seizure and/or injunction.

23. On October 11, 2002, the FDA issued a Warning Letter to Defendant K-V Pharmaceutical Company for marketing unapproved new drugs in violation of 21 U.S.C. § 355.

24. On March 2, 2009, the United States of America filed a Complaint for Permanent Injunction against Defendants seeking to prevent Defendants from manufacturing or selling pharmaceutical products due to persistent and long-standing violations of CGMP.

25. On or about March 3, 2009, Defendants entered a Consent Decree of Permanent Injunction in response to the Complaint filed on March 2, 2009 by the United States of America, and admitted that:

a. Defendants violated 21 U.S.C. § 331(a) by introducing into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(1)(2)(B), in that they have been manufactured, processed, packed, labeled, held, and distributed in violation of CGMP requirements;

b. Defendants violated 21 U.S.C. § 331(k) by causing the adulteration of drug products after shipment of one or more of their components;

c. Defendants violated 21 U.S.C. § 331(d) by introducing and delivering into

interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(I);

d. Defendants violated 21 U.S.C. § 331(a) by introducing and delivering into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

e. Defendants violated 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to be misbranded within the meaning of 21 U.S.C. § 352(f)(1).

26. In the Consent Decree for Permanent Injunction, Defendants agreed to, under the supervision of the FDA, destroy: (1) all drugs in Defendants' possession, custody, and control that are the subject of recalls announced by Defendants from May of 2008 through February of 2009, and (2) all other drugs in Defendants' possession, custody, and control, including all in-process drugs and drug components, as well as finished drugs.

27. In the Consent Decree, Defendants agreed to be permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing: the manufacture, processing, packing, labeling, holding, introduction, or delivery for introduction into interstate commerce at or from any of Defendants' facilities, of any drug, as defined in 21 U.S.C. § 321(g)(1), unless and until Defendants comply with certain requirements imposed by the FDA to ensure they are complying with CGMP and to ensure they are not manufacturing or selling non-approved, misbranded or adulterated drug products.

28. The United States District Court for the Eastern District of Missouri signed and entered the Consent Decree for Permanent Injunction on March 6, 2009.

29. Said Morphine tablets were adulterated, misbranded, defective, unreasonably dangerous and unfit for its intended uses. Defendants placed tens of thousands of patients, including Decedent, unnecessarily at risk of serious injury and/or death and may have caused them to suffer personal injuries and harm, including medical expenses, anxiety and fear induced from ingesting the defective and misbranded drug.

30. Defendants knew or should have known about the manufacturing and production defects, misbranding and negligent sale and distribution of the recalled Morphine and had a duty to design, develop, manufacture, produce, process, compound, formulate, test, sell, market, label, package, dose, advertise, promote, supply, release and/or distribute only safe Morphine tablets with approved doses of morphine and doses that were consistent with the dose on the label.

31. Defendants knew or should have known that they designed, developed, manufactured, produced, processed, compounded, formulated, tested, sold, marketed, labeled, packaged, dosed, advertised, promoted, supplied, released and/or distributed Morphine tablets with excessive and/or unapproved amounts of morphine sulfate and or amounts of morphine sulfate different from the amount on the label before:

- a. any of the tablets were released for distribution and sale; and,
- b. they mislabeled the recalled drug.

32. Defendants failed to implement or utilize adequate safeguards, tests, inspections and quality assurance procedures to ensure the accuracy of the strength of Morphine tablets, and that the dose of the drug was consistent with the drug's label.

33. Defendants failed to implement or utilize adequate testing, including batch testing, batch dose verification, and other procedures, safeguards, and inspections to confirm, monitor and

assess the quality, dose and safety of Morphine tablets.

34. Decedent was prescribed Morphine but unwittingly ingested the defective drug. As a direct and proximate result of the liability-producing conduct of Defendants and the defective and unreasonably dangerous condition of the Morphine tablets, the Plaintiffs have suffered injuries and damage.

35. As a direct and proximate result of the liability-producing conduct of Defendants and the defective and unreasonably dangerous condition of the Morphine tablets, the Plaintiffs seek reimbursement of the amounts of money spent for the purchase of the defective, misbranded and adulterated recalled Morphine.

36. As a direct and proximate result of the acts and omissions of Defendants, the Plaintiffs suffered serious physical injury, death, pain and suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital, surgical and funeral expenses and other expenses related to diagnosis and treatment thereof, for which Defendants are liable.

37. As a direct and proximate result of the acts and omissions of Defendants, the Plaintiffs have been prevented from pursuing her normal activities and employment, have experienced severe pain and suffering and mental anguish, and may have been deprived of her ordinary pursuits and enjoyments of life.

V. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence

38. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

39. Defendants, directly or indirectly negligently designed, developed, manufactured, tested, produced, labeled, inspected, packaged, dosed, distributed, promoted, marketed, advertised, released, or sold the Morphine tablets in the stream of commerce with a dose of the drug's active ingredients different from and/or exceeding the dose on the label, when it knew, or in the exercise of ordinary care, should have known that the drug posed a significant risk to the health, well-being and safety of the Plaintiffs, which risk was not known to Plaintiffs, or her prescribers.

40. At all times material hereto, Defendants had a duty to the Plaintiffs to exercise reasonable care in the design, development, manufacture, production, inspection, testing, labeling, packaging, distribution, promotion, marketing, supplying, advertisement, distribution or sale of Morphine tablets.

41. Defendants breached their duty and were negligent in their actions, misrepresentations, and omissions toward patients, Plaintiffs, and her prescribers, in that the Defendants:

a. failed to use reasonable care to design, develop, manufacture, produce, test, inspect, label, package, dose, promote, market, advertise, distribute, release or sell Morphine tablets that were safe for its intended and foreseeable uses, not defective, and not unreasonably dangerous;

b. sold, released, produced, and distributed of said Morphine tablets without

making proper and sufficient tests to determine the drug's strength/dose;

c. failed to use reasonable care to adequately warn foreseeable users such as Plaintiffs of the dangers of ingesting said Morphine tablets;

d. failed to use reasonable care to make reasonable tests and inspections, and/or evaluations necessary to discover such defects and unreasonably dangerous conditions associated with the said Morphine tablets;

e. failed to comply with and/or to use reasonable care to comply with standards of good manufacturing, production, inspection and testing practices, care including accepted industry standards, FDA recommendations, government regulations and statutes, in the design, development, manufacture, testing, inspecting, dosing, labeling, and otherwise production, distribution and release of said Morphine tablets;

f. failed to use reasonable care to timely remove and/or recall from the market, and/or otherwise prevent the continued contact of Plaintiffs with such defects and unreasonably dangerous conditions of said Morphine tablets;

g. failed to use reasonable care to investigate and/or use known and/or knowable reasonable alternative, manufacturing, production, testing and inspection processes for the said Morphine tablets;

h. failed to use reasonable care to warn Plaintiffs of dangers known and/or reasonably suspected to Defendants to be associated with said Morphine tablets;

i. failed to use reasonable care to make said Morphine tablets safe;

j. negligently representing that said Morphine tablets were safe for use for its intended purpose, when, in fact, it was not;

k. failed to use reasonable care to make reasonable tests, inspections and/or evaluations necessary to discover such defects and unreasonably dangerous conditions associated with said Morphine tablets;

l. failed to timely use reasonable care to discover the dangerous conditions or character of said Morphine tablets and recall the same; and

m. failed to use reasonable care to timely conduct a Recall of said Morphine tablets, and when the recall was implemented, it failed to use reasonable care to implement the recall and inform the medical community, and the public, including the Plaintiffs of all relevant information such that the chance of harm was minimized to the fullest extent possible.

42. Defendants knew or should have known that the said Morphine tablets caused unreasonably dangerous risks and serious side-effects, including death, of which Plaintiffs would not be aware.

43. Defendants nevertheless advertised, marketed, supplied, released, sold and distributed the drug knowing that there were safer products.

44. As a direct and proximate result of the negligence and breach of Defendants, Plaintiffs sustained serious injury and death. Defendants owed a duty to Plaintiffs to use reasonable care in its actions. Defendants' failure to use reasonable care proximately have caused Plaintiffs' injuries and death

45. As a direct and proximate result of Defendants' negligence, Plaintiffs were harmed as aforesaid.

SECOND CLAIM FOR RELIEF

Res ipsa loquitur

46. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

47. The design, development, manufacture, production, misbranding, adulteration, distribution, supply, testing, inspection, release or sale of a pharmaceutical with a dose of the drug's active ingredient that was different from the label and/or in excess of the dose on the label and sometimes in excess of the dose approved for human ingestion, to wit said Morphine tablets, is in and of itself an act that ordinarily bespeaks negligence.

48. During the time when it was being designed, developed, manufactured and produced, the instrumentality, said Morphine tablets, were within the Defendants' exclusive control before being released, supplied, distributed or sold to the public including the Plaintiffs. There is no indication in the circumstances set forth herein that the injuries that resulted from the ingestion of said Morphine tablets, was the result of Plaintiffs' own voluntary act or neglect.

49. The acts and omissions set forth herein are the type that ordinarily bespeak negligence and thus liability is established under the doctrine *res ipsa loquitur*.

50. Defendants had a duty to exercise reasonable care in the design, development, testing, manufacture, production, testing, inspection, labeling, packaging, supply, distribution, marketing, promotion, sale and release of said Morphine tablets, including a duty to not design, manufacture, produce, label, package, supply, distribute, market, promote, release or sell a pharmaceutical with doses of the drug's active ingredient that were in different from the dose on the label and/or in excess of the labeled dose and sometimes in excess of the dose approved for human ingestion, to wit said

Morphine tablets.

51. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs were harmed as aforesaid.

THIRD CLAIM FOR RELIEF
Negligence *Per Se*

52. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

53. At all times mentioned herein, Defendants had an obligation not to violate the law, in the design, development, manufacture, production, formulation, compounding, testing, inspecting, processing, assembling, testing, distribution, marketing, labeling, packaging preparation for use, release, sale and warning of the risks and dangers of the aforementioned product.

54. At all times herein mentioned, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301, et seq., related amendments and codes and federal regulations provided thereunder, and other applicable laws, statutes and regulations.

55. Plaintiffs, as a purchaser and consumer of said Morphine tablets, are within the class of persons the statutes and regulations described above are designed to protect, and the injuries alleged herein are the type of harm these statutes are designed to prevent.

56. Defendants' acts constitute an adulteration and misbranding as defined by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331, and the regulations promulgated therefrom and constitutes a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se*.

57. Defendants' manufacturing, production, testing and inspection processes are not good

manufacturing processes Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331 and the regulations promulgated therefrom and constitutes a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence per se.

58. The acts and omissions set forth herein, demonstrate that Defendants failed to meet the standard of care set by the applicable statutes and regulations, which were intended for the benefit of individuals such as Plaintiffs making Defendants negligent *per se*.

59. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs were harmed as aforesaid.

FOURTH CLAIM FOR RELIEF
Strict Product Liability – Defective Design

60. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein:

61. At all times material to this action, the Defendants were responsible for the design, development, manufacturing, production, testing, inspection, packaging, promoting, marketing, distributing, supply, labeling, release and/or sale said Morphine tablets.

62. Said Morphine tablets are defective and unreasonably dangerous to consumers and patients including Decedent. Said Morphine tablets are defective in design or formulation in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with their design and formulation.

63. At all times material to this action, said Morphine tablets were expected to reach, and did reach, consumers in the State of Oregon and throughout the United States, including the Plaintiffs herein, without substantial change in the condition in which it was sold.

64. At all times material to this action, said Morphine tablets were designed, developed, manufactured, produced, tested, packaged, promoted, marketed, distributed, labeled, released and/or sold by Defendants in a defective and unreasonably dangerous condition at the time were placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, said Morphine tablets contained an unreasonably dangerous design defect and was not reasonably safe as intended to be used, subjecting the Plaintiffs to risks that exceeded the benefits of the subject product, including but not limited to the risks serious bodily injuries and even death in an unacceptably high number of its users;

b. When placed in the stream of commerce, said Morphine tablets were defective in design and formulation, making the use of said Morphine tablets more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with other morphine medications and similar drugs on the market, including Morphine with approved doses of morphine, with doses that were consistent with the dose on the label;

c. Said Morphine tablets design defects existed before it left the control of the Defendants;

d. Said Morphine tablets were insufficiently tested and inspected;

e. Said Morphine tablets caused harmful side-effects that outweighed any potential utility; and

f. Said Morphine tablets were not accompanied by adequate instructions and/or warnings and labeling to fully apprise consumers, including the Plaintiffs, of the full nature and extent of the risks and side-effects associated with its use and that it contained an overdose of

morphine, and/or a dose different from the dose on the label, thereby rendering Defendants liable, individually and collectively, to the Plaintiffs.

65. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of injury to Plaintiffs without impairing the reasonably anticipated or intended function of the product. These safer alternative designs, including Morphine tablets with the approved dose of morphine, consistent with the dose on the label, were economically and technologically feasible, and would have prevented or significantly reduced the risk of injury to Plaintiffs without substantially impairing the product's utility.

66. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs were harmed as aforesaid.

FIFTH CLAIM FOR RELIEF
Strict Product Liability – Manufacturing Defect

67. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

68. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, producing, testing, packaging, inspecting, promoting, marketing, distributing, supplying, labeling, releasing and/or selling said Morphine tablets.

69. At all times material to this action, said Morphine tablets were expected to reach, and did reach, consumers in the State of Oregon and throughout the United States, including the Plaintiffs without substantial change in the condition in which they were sold.

70. At all times material to this action, said Morphine tablets were designed, developed,

manufactured, produced, tested, packaged, inspected, promoted, marketed, supplied, distributed, labeled, released and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, said Morphine tablets contained manufacturing defects which rendered the product unreasonably dangerous;

b. These manufacturing defects of said Morphine tablets occurred while the product was in the possession and control of the Defendants;

c. Said Morphine tablets were not made in accordance with the Defendants' specifications or performance standards and/or those specifications and standards approved by the FDA; and,

d. The manufacturing defects of said Morphine tablets existed before it left the control of the Defendants;

71. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs and were harmed as aforesaid.

SIXTH CLAIM FOR RELIEF
Strict Product Liability - Failure to Warn

72. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

73. Said Morphine tablets were defective and unreasonably dangerous when it left the possession of the Defendants in that it contained labeling, packaging and warnings insufficient to alert consumers, including the Plaintiffs, of the dangerous risks and reactions associated with said

Morphine tablets, including but not limited, failing to warn that said Morphine tablets contained a dose of morphine inconsistent with the dose on the label and sometimes a dose exceeding the approved dose for use by humans.

74. The Decedent was prescribed and used the subject product for its intended purpose.

75. The Plaintiffs could not have discovered any defect in the subject product through the exercise of reasonable care.

76. The Defendants, as designer, developer, manufacturers, producers, suppliers, inspectors, testers, distributors, releasers or sellers of the subject drug, a prescription drug, are held to the level of knowledge of an expert in the field.

77. The label, warnings, dosing strength information that were given by the Defendants with said Morphine tablets were not accurate, clear and/or were ambiguous.

78. The label, warnings, dosing and strength information that were given by the Defendants failed to properly warn physicians, the Plaintiffs, and the public that said Morphine tablets contained amounts of morphine that were inconsistent with the amount on the label and sometimes contained a dose not approved for use in humans and thus ingestion risked serious injuries, side effects and/or death.

79. The Plaintiffs, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

80. The Defendants had a continuing duty to warn the Plaintiffs of the dangers associated with said Morphine tablets.

81. Had the Plaintiffs received adequate warnings or information regarding the dose of morphine in said Morphine tablets and/or information regarding the risks of ingesting the subject

product, her would not have used it.

82. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs were harmed as aforesaid.

SEVENTH CLAIM FOR RELIEF
Strict Products Liability

83. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

84. At all relevant times, Defendants were the designers, developers, manufacturers, producers, makers, dosers, processors, compounders, formulators, labelers, packagers, testers, inspectors, distributor, marketers, promoters, suppliers, releasers and sellers of said Morphine tablets, which, at all relevant times, was defective and unreasonably dangerous to consumers.

85. At all relevant times, said Morphine tablets were defective in their design, manufacture and production in that they was not reasonably fit, suitable or safe for their intended purpose and/or their foreseeable risks exceed the benefits. Said Morphine tablets were defective in design, manufacture and production in that they posed a greater likelihood of injury than other properly-dosed morphine medicines and similar drugs on the market, and they were more dangerous than ordinary consumers could reasonably foresee.

86. At all relevant times, the defective condition of said Morphine tablets rendered it unreasonably dangerous, and said Morphine tablets were in this defective condition at the time it left the hands of the Defendants. Said Morphine tablets were expected to and did reach consumers, including Plaintiffs, without substantial change in the condition in which it was designed, developed, manufactured, labeled, dosed, produced, sold, distributed, marketed, promoted, supplied and

otherwise released into the stream of commerce.

87. At all relevant times, Plaintiffs were unaware of the significant hazards and defects in said Morphine tablets. Said Morphine tablets were unreasonably dangerous than would be reasonably contemplated by the ordinary user. During the period that were taking said Morphine tablets, the medication was being utilized in a manner that was intended by the Defendants. At the time Plaintiffs received and consumed said Morphine tablets, it was represented to be safe and free from latent defects and was to have an approved dose of morphine consistent with the does set forth on the label.

88. At all relevant times, Defendants knew or should have known of the danger associated with the use of said Morphine tablets, as well as the defective nature of said Morphine tablets, but continued to manufacture, sell, distribute, label, package, market, promote, release and/or supply said Morphine tablets so as to maximize sales and profits at the expense of the public health and safety and to maintain its brand integrity, in conscious disregard of the foreseeable harm caused by said Morphine tablets.

89. At all relevant times, said Morphine tablets were in a defective and unreasonably dangerous condition which would not be recognized or contemplated by a reasonable person among the expected users and consumers at the time it left the control of the Defendants.

90. At all relevant times, said Morphine tablets were defective and unreasonably dangerous when used in reasonably expectable ways of handling and/or consumption.

91. At all relevant times, said Morphine tablets were expected to reach, and did reach, the ultimate user or consumer without substantial change in the condition in which it was sold, supplied, manufactured, produced, and/or distributed by Defendants.

92. At all relevant times, said Morphine tablets were defective and unreasonably dangerous under section 402(A) Restatement (Second) of Torts.

93. Defendants are strictly liable to Plaintiffs for manufacturing, producing and placing into the stream of commerce a product which was defective and unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants.

94. As a direct and proximate result of Defendants' defective and unreasonably dangerous products, Plaintiffs were harmed as aforesaid.

EIGHTH CLAIM FOR RELIEF
Breach of Express Warranty

95. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

96. At all relevant times, Defendants warranted that said Morphine tablets were safe and not defective and/or unreasonably dangerous as stated above and warranted that it contained a dose of morphine consistent with the dose set forth on its label and was otherwise safe for human ingestion.

97. At all relevant times, Defendant placed said Morphine tablets into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including the Plaintiffs, of the risks associated with the use of said Morphine tablets and that it contained an amount of morphine exceeding labeled dose and sometimes exceeding the approved dose for human ingestion.

98. At all relevant times, Defendants had a duty to exercise reasonable care in the design, development, testing, manufacture, production, formulation, processing, compounding, labeling,

packaging, inspections, supply, distribution, marketing, promotion, sale and release of said Morphine tablets, including a duty to:

- a. Ensure that the product did not cause the user unreasonably dangerous side-effects;
- b. Ensure that the product was labeled accurately;
- c. Ensure that the amount, strength and dose of the morphine in the product was consistent with the that set forth on the label and to ensure that the does was approved by the FDA as a dose safe for use in humans;
- d. Warn of dangerous and potentially fatal side-effects; and,
- e. Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiffs.

99. When the physicians of the Plaintiffs prescribed said Morphine tablets and the Plaintiffs decided to use said Morphine tablets, both Plaintiffs, and her physicians reasonably relied upon the Defendants and their agents to disclose known defects, risks, dangers and side-effects of said Morphine tablets and whether said Morphine tablets contained a dose of morphine, consistent with its label, and not in excess, or different from the of the dose approved for ingestion by humans.

100. Plaintiffs' physician(s), the FDA and/or Plaintiffs had no knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning said Morphine tablets when Plaintiffs' physician(s) prescribed and/or otherwise provided Recalled Morphine and Plaintiffs purchased and used said Morphine tablets as designed, developed, tested, manufactured, produced, dosed, inspected, labeled, packaged, distributed, supplied, marketed, promoted, sold and otherwise released into the stream of commerce by the Defendants. Plaintiffs justifiably and detrimentally

relied on the warranties and representations of Defendants in the purchase and use of said Morphine tablets.

101. At all relevant times, Defendants were under a duty to disclose the defective and unsafe nature of said Morphine tablets to physicians, the FDA, consumers and users, such as the Plaintiffs. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians, the FDA and users, such as Plaintiffs, could not have reasonably discovered such defects.

102. By the conduct alleged, Defendants, its agents and employees expressly warranted to Plaintiffs and her physicians(s) that said Morphine tablets were packaged and labeled accurately that it contained the approved dose of morphine, that the drug was safe, merchantable and fit for the purpose intended.

103. This warranty was breached because said Morphine tablets were misbranded, adulterated and did not contain the amount of morphine as stated in the label and sometimes the approved dose for ingestion by humans, nor was it safe and effective as Defendants represented, and Plaintiffs were harmed as aforesaid.

104. As a direct and proximate result of Defendants' defective and unreasonably drug and their breach of express warranty, Plaintiffs were harmed as aforesaid and plaintiffs have suffered damages including death.

NINTH CLAIM FOR RELIEF
Breach of Implied Warranty

105. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein

106. The Defendants designed, developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold said Morphine tablets for the treatment of pain.

107. At the time that the Defendants designed, developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold said Morphine tablets, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

108. The Plaintiffs, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

109. The Decedent was prescribed, purchased, and used said Morphine tablets for its intended purpose.

110. Due to the Defendants' wrongful conduct as alleged herein, the Plaintiffs could not have known about the mislabeling, misbranding, nature of the risks and side-effects associated with said Morphine tablets until after the Decedent used it.

111. Contrary to the implied warranty for the subject product, said Morphine tablets were not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

112. As a direct and proximate result of the acts and omissions of Defendants and the defective and unreasonably dangerous Morphine tablets and their breach of implied warranty, Plaintiffs were harmed as aforesaid, and Plaintiffs have suffered injuries and damages including death.

TENTH CLAIM FOR RELIEF
Misrepresentation and Suppression by Defendants

113. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein:

114. Defendants misrepresented to Plaintiffs and the medical community the safety and effectiveness of said Morphine tablets and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of said Morphine tablets and the dose of morphine contained therein.

115. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that said Morphine tablets had defects, dangers, and characteristics that were other than that what the Defendants had represented to Plaintiffs, the public, the FDA and the medical community generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiffs, the FDA and, the medical community and consuming public that:

- a. Some of said Morphine tablets were not a dose that was approved by the FDA;
- b. The dose strength of the morphine in said Morphine tablets were not what the label represented the dose strength to be;
- c. Some of doses of morphine in said Morphine tablets exceeded the dose approved for use in humans;
- d. The dose of morphine in said Morphine tablets were unsafe, hazardous and dangerous; and,
- e. Ingesting said Morphine tablets would result in an overdose, underdose or a

dose different from the dose on the label..

116. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

117. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that Plaintiffs would rely on them, leading to the use of said Morphine tablets.

118. At the time of Defendants' fraudulent misrepresentations, Plaintiffs were unaware of the falsity of the statements being made and believed them to be true. Plaintiffs had no knowledge of the information concealed and/or suppressed by Defendants.

119. Plaintiffs justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to the detriment of the Plaintiffs.

120. Defendants had a duty to warn Plaintiffs, the public, the FDA and the medical community, about the misbranding, adulteration and potential risks and complications associated with said Morphine tablets in a timely manner but failed to do so.

121. The misrepresentations and active fraudulent concealment by the Defendants constitutes a continuing tort against the Plaintiffs who ingested said Morphine tablets.

122. Defendants made the misrepresentations and actively concealed information about the defects and dangers of said Morphine tablets with the intention and specific desire that the healthcare professionals treating the Plaintiffs, the Plaintiffs, and the consuming public would rely on such or the absence of information in selecting and using said Morphine tablets as a medical treatment.

123. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiffs have suffered injuries and damages including death.

ELEVENTH CLAIM FOR RELIEF

Fraud

124. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

125. Defendants fraudulently, intentionally, wilfully and wantonly, purposefully, knowingly, recklessly, negligently and/or in fact materially misrepresented both affirmatively and by omission that said Morphine tablets were of good quality, non-defective, safe for its intended use, merchantable, and fit for its particular purposes.

126. Defendants intended, knew, and/or should have known that Plaintiffs would be induced, by the aforesaid misrepresentations, to use said Morphine tablets.

127. In using said Morphine tablets, Plaintiffs justifiably relied on Defendants' representations that its Recalled Morphine was of good quality, non-defective, labeled accurately, not adulterated and was safe for its intended use, merchantable, and fit for its particular purposes.

128. Said Morphine tablets were, in fact, misbranded, adulterated, defective and unreasonably dangerous, as recited above.

129. As a direct and proximate result of the defective and unreasonably dangerous Morphine tablets as well as its affirmative misrepresentations and omissions, Plaintiffs were harmed as aforesaid and Plaintiffs suffered injuries and damages including death.

TWELFTH CLAIM FOR RELIEF
Negligent Misrepresentation

130. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

131. Defendants, in addition to knowing misrepresentations, made misrepresentations without any reasonable grounds for believing their statements to be true to Plaintiffs, other patients, and the medical community.

132. Defendants, through its misrepresentations, intended to induce justifiable reliance by Plaintiffs, other patients, and the medical community.

133. Defendants, through its labeling, marketing campaign and communications with treating physicians, was in a relationship so close to that of Plaintiffs and other patients that it approaches and resembles privity.

134. Defendants owes a duty to the medical community, Plaintiffs and other consumers, to conduct appropriate and adequate inspections and tests for all of their products, including said Morphine tablets, and to use safe and good manufacturing and production practices, to provide appropriate and adequate information and warnings but they failed to do so.

135. Defendants failed to conduct appropriate or adequate inspections and/or tests on said Morphine tablets.

136. As a direct and proximate result of the defective and unreasonably dangerous Morphine tablets as well as its affirmative misrepresentations and omissions, Plaintiffs were harmed as aforesaid and Plaintiffs suffered injuries and damages including death.

THIRTEENTH CLAIM FOR RELIEF
Consumer Fraud

137. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

138. At all relevant times, Defendants knew or should have known that the use of said Morphine tablets caused serious and life-threatening injuries and death but failed to warn the public, including the Plaintiffs of the same.

139. At all relevant times, Defendants made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from Plaintiffs, the FDA, the public and the medical community in the product packaging, labeling, advertising, direct-to-consumer advertising, promotional campaigns and other materials, among other ways, regarding the safety and amount of morphine in said Morphine tablets. Moreover, Defendants downplayed and/or understated the serious nature of the risks associated with Recalled Morphine in order to increase the sales of said Morphine tablets and maintain their share of the morphine market and maintaining the integrity of their brand.

140. At all relevant times, Defendants' statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including the Plaintiffs would rely on the Defendants' statements and/or omissions.

141. Plaintiffs were prescribed and/or otherwise provided with, and consumed, said Morphine tablets and have or may have suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts or practices or failure to act, alleged herein.

142. The aforesaid misbranding, adulteration, supply, distribution and sale and release of

said Morphine tablets into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression or omission in connections with the sale or advertisement of such merchandise or services by Defendants.

143. At all relevant times, Defendants concealed, omitted, or minimized that the Recalled Morphine had an amount of morphine inconsistent with the stated dose on the label and sometimes exceeding the approved dose for use in humans or provided mis-information about adverse reactions, risks and potential harms from said Morphine tablets and succeeded in persuading consumers, including Plaintiffs to purchase and ingest said Morphine tablets despite the lack of safety and the risk of adverse medical reactions, including but not limited to those set forth in the Morphine label.

144. At all relevant times, Defendants practice of promoting and marketing said Morphine tablets created and reinforced a false impression as to the safety of said Morphine tablets, thereby placing consumers, including Plaintiffs at risk of serious and potential lethal effects.

145. At all relevant times, said Morphine tablets lacked appropriate warnings and information about the dose strength of the drug, and the packaging and labels used by Defendants were misleading, inaccurate, incomplete and/or untimely.

146. Defendants violated their post-manufacture duty to warn which arose when it knew, or with reasonable care should have known, that said Morphine tablets were injurious and sometimes fatal.

147. At the time when consumers, including the Plaintiffs, purchased and ingested said Morphine tablets, Defendants intended that others would rely upon the concealment, suppression or

omission of the risks of ingesting said Morphine tablets.

148. Defendants' actions in connection with design, development, manufacture, production, labeling, packaging, supplying, testing, inspecting, distributing, marketing, release and sale of said Morphine tablets as set forth herein evidence a lack of good-faith, honesty in fact and were not observant of fair dealing so as to constitute unconscionable commercial practices.

149. Defendants acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

150. As a proximate result of the acts of consumer fraud set forth above, Plaintiffs purchased and ingested an unsafe, misbranded, adulterated, product and incurred monetary expense and the risk to themselves and members of her households that they would consume said Morphine tablets and thereby suffer an increased risk of harm as previously set forth herein.

151. The conduct of the Defendants, as set forth above, constitutes unfair, deceptive, unlawful, and/or unconscionable acts and/or practices prohibited under the law the Consumer Protection Statutes of the State of Oregon.

152. As a direct and proximate result of Defendants' unfair, deceptive, unlawful, and/or unconscionable acts or practices in violation of the aforesaid Consumer Protection Laws, as well as its affirmative misrepresentations and omissions, Plaintiffs were harmed as aforesaid and Plaintiffs suffered injuries and damages including death.

FOURTEENTH CLAIM FOR RELIEF
Unjust Enrichment

153. Plaintiffs incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

154. Defendants accepted payment from Plaintiffs for the purchase of said Morphine tablets.

155. Plaintiffs did not receive a safe and effective drug for which they paid and as aforesaid, received a dangerous and defective drug.

156. It would be inequitable for Defendants to retain this money because Plaintiffs did not in fact receive a safe and effective drug.

FIFTEENTH CLAIM FOR RELIEF
Wrongful Death

157. Plaintiffs incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

158. The Plaintiffs bring this claim on behalf of themselves and the Decedents' lawful beneficiaries. As a direct and proximate result of the conduct of the Defendants and/or the effective nature of said Morphine tablets as outlined above, Decedent suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses of hospitalization, medical and nursing care and treatment, loss of earnings as well as loss of ability to earn money, and death. As a direct and proximate result of the conduct of the Defendants, the Decedent incurred hospital, nursing and medical expenses. The Plaintiffs have incurred hospital, nursing, medical, funeral and estate administration expenses as a result of Decedent's death.

159. The Plaintiffs have paid and/or have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future.

160. The Plaintiffs have been caused, presently and in the future, to suffer the loss of their

loved one's companionship, services, society, marital association, love and consortium and accordingly, Plaintiffs have suffered greatly.

SIXTEENTH CLAIM FOR RELIEF

Survival Action

161. Plaintiffs incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

162. As a result of the actions and inactions of the Defendant, Decedent was caused to suffer before his death. As a direct and proximate result of the conduct of the Defendants, Decedent, prior to his death, was obliged to spend various sums of money to treat his injuries, which debts have been assumed by Decedent's Estate. As a direct and proximate result of the aforesaid, Decedent was caused pain, suffering, mental anguish and impairment of the enjoyment of life, until the date of his death; and as a direct and proximate result of the aforesaid, Decedent suffered loss of earnings and earning capacity.

163. The Plaintiffs as Representative or Administrator of Decedent's Estate, brings this claim on behalf of Decedent's Estate for damages.

164. As a direct and proximate result of the conduct of the Defendants, Decedent and the Plaintiffs, until the time of Decedent's death, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of physiological stress and disorder. This claim is brought on behalf of the Estate of Decedent.

165. As a direct and proximate result of the Defendants, and including the observance of the suffering of the Decedent, the Plaintiffs suffered permanent and ongoing physiological damage.

The Plaintiffs have and will continue to suffer permanent and ongoing psychological damage.

166. Plaintiffs, on behalf of the Decedent's estate, seeks damages compensable against Defendants.

SEVENTEENTH CLAIM FOR RELIEF
Punitive Damages

167. Plaintiffs incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

168. Defendants knew or should have known of the defective nature of said Morphine tablets and associated dangers of its use but continued to design, manufacture, sell, distribute, market, promote and/or supply the drug so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the drug.

169. Defendants before and/or after making the drug available for the public use, knowingly withheld from or misrepresented to the FDA, patients or prescribing physician information about the risks of using the drug that were known to be material and relevant to the described injuries suffered by the Decedent.

170. Defendants, in one or more of the acts or omissions previously alleged, has acted with malice or with reckless and outrageous indifference to a highly unreasonable risk of harm and has acted with a conscious indifference to the health, safety and welfare of others, including Decedent and the Plaintiffs.

171. Punitive damages should be awarded against Defendants in an amount to be determined by a jury at trial in accordance with the law.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants for damages as follows:

1. For fair and reasonable non-economic damages sustained by the Decedent's beneficiaries for the loss of his society and companionship in an amount to be determined by a jury at trial;
2. For fair and reasonable economic damages sustained by the Decedent's beneficiaries for the loss of services and support they would have received but for his untimely death in an amount to be determined by a jury at trial;
3. For fair and reasonable economic damages sustained by the Decedent's Estate and his heirs because of his untimely death and his funeral and burial expenses.
4. For reasonable attorneys' fees and costs and expert fees;
5. For restitution of all purchase costs that Plaintiffs incurred for Morphine and for disgorgement of Defendants' profits;
7. For exemplary and punitive damages in an amount in excess of the jurisdictional limits, trebled on all applicable Counts, to punish the Defendants for their conduct;
8. For costs and disbursements incurred herein; and
9. For any other relief as the Court may deem equitable and just.

VII. JURY TRIAL DEMANDED

Plaintiffs demand that all issues of fact of this case be tried to a properly impaneled jury.

Dated this 12th day of May, 2009

JOHNSON, CLIFTON, LARSON & SCHALLER, PC.

/s/ Derek C. Johnson

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